

FDA clears Evolva's IND for EV-077 in influenza

Reinach, Switzerland, 28 March 2011 – Evolva Holding SA (SIX: EVE) today announced that the US Food and Drug Administration (FDA) has cleared Evolva's request to test EV-077 in man, under an Investigational New Drug (IND) application for influenza.

Neil Goldsmith, CEO and Managing Director of Evolva commented: "This regulatory clearance by the FDA is an important milestone in the development of EV-077. In preclinical testing, EV-077 has shown potential as prophylaxis and treatment of various viral infections. We believe the compound could have significant potential against influenza and in bio-defence."

Evolva has entered into discussions with potential partners regarding the further development and marketing of the compound. Evolva owns the rights to all intellectual property surrounding EV-077.

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About EV-077

In addition to the development of EV-077 for complications of diabetes, Evolva has (partly under its existing program with US Defense Threat Reduction Agency) been investigating a novel anti-viral property of this dual thromboxane receptor antagonist and thromboxane synthase inhibitor. Many viruses, upon infecting a host, cause an increase in prostanoids. This impairs the host's immune response and thus helps the virus survive and prosper in the host. As EV-077 does not directly interact with the virus it is expected to be less prone to the development of resistance by the virus.

EV-077 has been studied in pre-clinical models of influenza A, administered orally twice daily starting one day before exposure to the virus, and also one hour and one day after exposure. Oseltamivir (Tamiflu®, Roche) served as positive control, and was also used in combination with EV-077.

In vivo prophylactic studies demonstrated that EV-077 reduced clinical disease scores in a similar manner to Tamiflu®. However, when treatment started after overt clinical signs (1 day post-exposure), EV-077 was more efficacious than Tamiflu® in reducing lung consolidation (20 vs. 30%), viral titers (75 vs. 250 pfu/lung) and clinical disease scores (70 vs. 30% reduction).

In a second gold standard model of influenza, the reduction in lung consolidation was also more pronounced with EV-077 than with Tamiflu®. Moreover, in both models, the combination of Tamiflu® with EV-077 provided added benefits over each treatment alone on all parameters tested.

About Evolva Holding SA

Evolva is an international, innovative synthetic biology company with a world-class research platform. Evolva strives to improve people's lives by applying its technology and other resources to the discovery and development of new products and processes that benefit the health, well-being and financial economy of patients, consumers and partner companies around the world. Evolva uses biosynthetic and evolutionary technologies to artificially create and optimise small molecule compounds and their production routes. Our approach differs from that of the mainstream in the pharmaceutical and chemical industries. We have discovery partnerships ongoing both in Pharma and in the area of Consumer Health, Nutrition and Food Chain. In addition we have a pipeline of promising compounds aimed at infectious and cardio-renal indications. For more information see www.evolva.com.

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